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December 3, 1999

Document Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Sir:

I am writing in regards to **Docket No. 97N-484S** dealing with a proposal to regulate allograft tissue³

There is absolutely no reason to regulate this type of material, which has been used successfully by surgeons for many years and is already regulated by the FDA as tissue. There is no additional reason to regulate bone allograft as a medical device. To do so would impose a significant burden on bone banks and in all likelihood curtail the supply of bone products that are used by surgeons to treat spinal and other skeletal conditions.

I hope that the FDA will reject this proposed regulation.

Sincerely,

Russell W. Hardy, Jr., M.D.

RWH/yli

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97N-484S

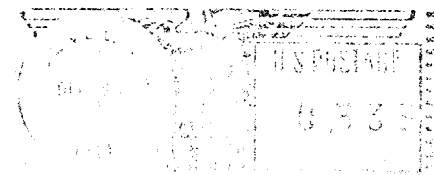
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